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## **Summary of Safety and Efficacy**

510(k) Summary for the CAP-35BIII and CINE 275 Cineangiogram Projectors

Prepared February 6, 1997

This summary of 510(k) safety and efficacy  
information is being submitted in compliance with the requirements of SMDA 1990 and CFR  
807.92.

### **Submitter's Name**

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### **Device Name and Classification**

Trade name: CAP-35BIII and CINE 275 Cineangiogram Projectors  
Common name: 35 mm Cineangiogram Projector  
Classification: Angiographic X-Ray System, 21 CFR 892.1600

### **Predicate Device**

The CAP-35BIII and CINE 275 projectors are substantially equivalent to the Vanguard XR-350 cineangiogram projector manufactured which was declared substantially equivalent on October 5, 1995.

### **Description of the CAP-35BIII and CINE 275 Cineangiogram Projectors**

The CAP-35BII cineangiogram projector is a continuous film transport 16-facet rotating prism projectors. The CINE 275 is a simpler version of the CAP-35BIII, with fewer options. The CAP-35BIII consists of a 35 mm film projector with built-in viewing hood, a movable cart, a sheet film duplicator, a 35 mm slide camera, a remote control, and an optional TV camera assembly. The CINE 275 consists of a 35 mm film projector with built-in viewing hood and a movable cart.

### **Intended Use**

The CAP-35BIII and the CINE 275 are intended to be used to view 35 mm cineangiogram film.

**Table of Comparisons between the CAP-35BIII, CINE 275, and Vanguard XR-350**

<b>Characteristic</b>	<b>CAP-35BIII</b>	<b>CINE 275</b>	<b>Vanguard XR-350</b>
Intended use	Viewing 35 mm angiographic film	Viewing 35 mm angiographic film	Viewing 35 mm angiographic film
Major system components	Projector Cart Remote control 35 mm slide film camera 8" X 10" camera	Projector	Projector Viewing hood Powered mobile cart
Options	CCD TV camera	Cart	NTSC TV camera
Light source	Halogen lamp	Halogen lamp	Xenon arc lamp
Film transport	Continuous film advance, 16-facet rotating prism	Continuous film advance, 16-facet rotating prism	Intermittent claw advance
Projector dimensions	Width 24 in.      Height 24.4 in. Depth 27 in.      Weight 132 lb.	Width 20 in.      Height 20.3 in. Depth 21.3 in.      Weight 66 lb.	Width 26 in.      Height 29 in. Depth 35.5 in.      Weight 147 lb.
Power	120 V 60 Hz 5 A	120 V 60 Hz 4.5 A	115 V 60 Hz 10 A
Film capacity	35 mm X 656 ft.	35 mm X 500 ft.	35 mm X 500 ft.
Projection optics	57-92 mm lens f/4.5 varifocal	50 mm lens f/4.5	65 mm lens f/3.0
Image size	11 in. x 8.1 in	10 in. x 8 in	11.25 in. x 9.50 in.
Modes of operation	Variable speed from 3-100 fps Single-frame advance Forward/reverse Rewind Fast forward	Variable speed from 3-80 fps Single-frame advance Forward/reverse Rewind Fast forward	Variable speed: 1, 4, 7, 10, 15, 30 fps Single-frame advance Forward/reverse Rewind Fast forward
Features	Push-button focus Push-button framing Push-button trimming Push-button zoom LED frame counter Selectable auto-stop	Manual focus Manual framing Selectable auto-stop	Push-button focus Manual framing LED frame counter Auto-stop Image rotation